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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,664	02/06/2002	Chuan Li	ETI.PMMU.011502	8973

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EXAMINER	
KETTER, JAMES S	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/068,664	LI, CHUAN	
	Examiner	Art Unit	
	James S. Ketter	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) 6-15 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-5 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 06 February 2002 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 1/12/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's election without traverse of Group I, claims 1-5, in the Paper filed 12 January 2004 is acknowledged.

Claims 6-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the Paper filed 12 January 2004.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Stemmer (cited of record in the Information Disclosure Statement filed 12 January 2004, now numbered as reference 5).

Claim 1 is drawn to a plasmid, recited as de novo synthesized, which comprises a replication origin and a selection marker gene. Claim 2 recites a plasmid of claim 1, wherein the plasmid is not modified from the plasmid previously obtained from natural sources. This limitation is not clear—please see the rejection, below, under 35 USC 112, second paragraph. As such, for purposes of this rejection, it is understood that a plasmid not modified from that as taught would meet this claimed limitation. Claim 3 recites a plasmid of claim 1, wherein the plasmid is not modified from the plasmid previously obtained from recombinant sources. This limitation is not clear—please see the rejection, below, under 35 USC 112, second paragraph. As such, for purposes of this rejection, it is understood that a plasmid not modified from that as taught would meet this claimed limitation. Claim 4 is drawn to a plasmid of claim 1, wherein the replication origin allows autonomous replication. Claim 5 is drawn to a plasmid of claim 1 wherein the selection marker encodes a product indicative of plasmid maintenance in the host cell. The term "indicative" is taken to encompass "causative", as the growth of the cell on selective medium is itself indicative of presence of the plasmid.

Stemmer et al. teaches, e.g., as summarized in the Abstract of the reference, and specifically at Figures 1 or 3, a plasmid made synthetically. At page 50, left-hand column, first three paragraphs, it is taught that pUC322-Sfi employed pBR322 sequences, which would inherently include the replication origin. At the legend of Figure 1, it is taught that the plasmid was cloned into E. coli, indicating that an origin was present. Figure 1 also shows the presence of two selectable marker genes. Similarly, Figure 3 teaches pUC182Sfi, synthesized from fragments. The paragraph bridging the left-hand column of page 50 and the left-hand column of page 51 teaches that this plasmid has the features of pUC18, which were well known in the art to include a marker gene and an origin of replication.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 2 may be interpreted to mean that no part of the claimed plasmid derives from a naturally obtained plasmid sequence. However, this would mean that the origin of replication and the selection marker did not originate in nature. There is no description of any such origin of replication or selection marker in the specification of the present application. Furthermore, it is

not apparent that any artificial origins or markers were known in the art, let alone the broad genus of each encompassed by the claim. Still further, the art of modification of existing proteins to perform a particular function is largely devoid of useful rules, algorithms or formulae permitting reliable design of new proteins. Thus, the art is all the more deficient in permitting the completely de novo design of the replication machinery needed for a new origin or of a new enzymatic marker for selection purposes. One of skill in the art would not have recognized that Applicant was in possession of any such origins or markers at the time of filing of the application, and certainly not the broad genus of each encompassed by the claim. As such, the claim lacks adequate written description.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, and therefore claims 2-5 which depend therefrom, is drawn to a "de novo synthesized plasmid". However, it is not clear from either the specification or the prior art whether this term means that the plasmid is entirely fabricated from DNA which was synthesized chemically, and/or whether the sequences created in the plasmid were designed without reference to existing sequences which themselves derived from nature. As such, the scope of each of the claims is unclear.

Furthermore, with respect to claims 1-5, the phrases "sequences relevant to...replication" and "sequences relevant to...selection" found in "(a)" and "(b)", respectively, of claim 1 are unclear. Specifically, it is not clear what relevance to a biological process means, i.e., whether the sequences to which the phrases refer are active in causing replication or selection, whether they merely exert control over those processes, or whether they have some indirect role of a more general metabolic nature. As such, the scope of the claims with respect to the identities of these sequences is unclear.

Claim 2 recites "the plasmid is not modified from the plasmid previously obtained from natural sources. **First**, it is not clear to what plasmid the second reference to "the plasmid" refers, i.e., there is not proper antecedent basis for this term. As such, this limitation has no apparent context and conveys no meaning. **Second**, the entire phrase is unclear in that it has multiple possible interpretations, which are somewhat contradictory. For example, it may mean that the claimed plasmid has the same sequence as a plasmid isolated from or existing in nature, or it may mean that the claimed plasmid has no sequence in it identical to a sequence found in a natural plasmid, or it may mean that the sequences of the referenced, but undefined plasmid of the second part of the phrase, only, are excluded. Care should be taken in considering how the claim might be rewritten to clarify the invention Applicant wishes to claim.

Claim 3 recites "the plasmid is not modified from the plasmid previously obtained from recombinant sources. **First**, it is not clear to what plasmid the second reference to "the plasmid" refers, i.e., there is not proper antecedent basis for this term. As such, this limitation has no apparent context and conveys no meaning. **Second**, the entire phrase is unclear in that it has multiple possible interpretations, which are somewhat contradictory. For example, it may mean

that the claimed plasmid has the same sequence as a plasmid previously constructed in a laboratory, or it may mean that the claimed plasmid has no sequence in it identical to a sequence found in a plasmid previously constructed in a laboratory, or it may mean that the sequences of the referenced, but undefined plasmid of the second part of the phrase, only, are excluded. Care should be taken in considering how the claim might be rewritten to clarify the invention Applicant wishes to claim.

Claim 4 uses the word "the" before "autonomous". However, this usage implies an antecedent basis for the term "autonomous plasmid replication", which basis is absent. Applicant should delete "the" in this instance, which would clarify the meaning of the claim.

Certain papers related to this application, OTHER THAN OFFICIAL RESPONSES, may be submitted directly to the Examiner by facsimile transmission at (571) 273-0770. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993)(see 37 CFR ' 1.6(d)). (703) 872-9306 may be used without notification of the Examiner, with such faxed papers being handled in the manner of mailed responses. Applicant is encouraged to use the latter fax number unless immediate action by the Examiner is required, e.g., during discussions of claim language for allowable subject matter. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (571) 272-0770. The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (571) 272-0781.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Jsk
March 17, 2004

JAMES KETTER
PRIMARY EXAMINER